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10/591,737	08/06/2007	Peter Mullejans	P71419US0	3138
136	7590	12/02/2009	EXAMINER	
JACOBSON HOLMAN PLLC			HANRAHAN, BENEDICT L	
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			12/02/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/591,737	MULLEJANS ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	BENEDICT L.C. HANRAHAN	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 24 September 2007.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) 14 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-13 and 15-28 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>9/11/2007</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13 and 15-28, drawn to an ostomy appliance and a method of applying an ostomy appliance.

Group II, claim(s) 14, drawn to a method for the preparation of inner bag liner.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The method of preparation for the inner bag liner is not specific to the inner bag liner of Group II. Any inner bag liner may be used in the method disclosed in Group II.

3. During a telephone conversation with Harvey Jacobson on 11/29/2009 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-13 and 15-28. Affirmation of this election must be made by applicant in replying to this Office action. Claim 14 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-4, 7-13, 15, 16, 20-22 and 24-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/549,567. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending Application '567 discloses all of the claimed subject matter including additional limitations as disclosed by applicant in claims 1-4, 7-13, 15, 16, 20-22 and 24-26. The current pending application claims do not specifically disclose that the fold lines form spiral lines. However, the inner bag liner of Smith would be capable of having spiral lines in its compacted position. Applicant has not provided what is the criticality of having the fold lines be spiral in shape. When comparing the two sets of claims, Examiner used copending Application '567's most recent claims that were filed on 6/30/2009.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Objections***

7. Claim 23 is objected to because of the following informalities: In line 2 of claim 23, "plane" is believed to be misused and should instead state "planar". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 27 appears to have two preambles. It is also unclear if applicant is trying to claim a product or a method of making the product. If applicant is attempting to claim the product, claim 27 needs to be amended. If applicant is attempting to claim the method, the claim needs to be rewritten in independent form. It will then be restricted because it is a near duplicate of claim 14, which has also been restricted.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-6, 8-12, 15-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,591,144; hereinafter Smith).

13. Regarding claim 1, Smith discloses an ostomy appliance comprising a base plate in the form of a flange 3, said base plate having a first hole for receiving a stoma, ureter, or catheter and an adhesive wafer 4 having a first surface to be attached to the wearer's abdomen, back, or chest (Fig 5); a receiving member 1 releasably attached to the base plate 3 via double sided tape 12, said member 1 having a second hole for receiving wastes exiting the stoma, ureter or catheter (Fig 2); and a disposable inner bag liner 2 forming a second bag inside the receiving member 1 and being releasably attachable to the base plate 3 in a first coupling area by first coupling means, said disposable inner bag liner 2 having a third hole for receiving wastes exiting the stoma, ureter or catheter and the receiving member 1 being releasably attachable to the base plate 3 in a second coupling area by second coupling means, the first coupling means being in the form of an adhesive flange projecting from a rim of the third hole (indicated generally at item 2a in Fig 2A) and having a surface for releasable sealing against a second surface of the base plate 3 facing away from the user, wherein the inner bag liner 2 is provided with folding lines for compacting the bag lengthwise (Fig 2) (See also Cols 4 and 5 all lines).

Smith teaches that inner bag liner 2 is welded to base plate 3 (first coupling means) and thus does not teach that the bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling means. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer bag 1 to the base plate 3. Therefore, it would be obvious to one of ordinary skill in the art to modify the article of Smith such that bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling

means, i.e. the adhesive flange projecting from the rim of said third hole, with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2. The first coupling means of the article fairly suggested by Smith has a surface for releasable sealing against a first surface of the adhesive wafer and is in the form of an adhesive flange.

Smith does not specifically disclose that the fold lines form spiral lines. However, the inner bag liner of Smith would be capable of having spiral lines in its compacted position. Applicant has not provided what is the criticality of having the fold lines be spiral in shape.

14. Regarding claim 2, Smith discloses that the second coupling means 12 is in the form of an adhesive flange projecting from the rim of the second hole and having a surface for adhesive sealing against the second surface of the base plate 3 (Col 4, lines 39-41). Thus, because the first and second coupling means meets all of the structural limitations of claim 1 and 2, the first and second coupling means are necessarily configured to allow the inner bag liner to be removed and replaced with a new inner bag liner while reusing the receiving bag.

15. Regarding claim 3, Smith does not teach that an outer diameter of the first coupling means is greater than an inner diameter of the second coupling means. However, increasing the length of said first coupling means (i.e. the flange in the marked Fig. 2A of Smith shown below) such that the outer diameter is greater than the inner diameter of second coupling means 12 would provide more surface area for adhesion of bag liner 2 to base plate 3, thus providing more securement for the receiving member/bag while in use as the flow of exudates applies force to the bag liner, preventing the bag liner 2 from becoming prematurely detached. It would be obvious to one of ordinary skill in the art to modify the article of Smith so as the lengthen the

adhesive flange of bag liner 2 projecting from the rim of said third hole such that the outer diameter of the flange, i.e. the first coupling means, is greater than the inner diameter of second coupling means 12 to provide stronger securement of the bag liner to the base plate to prevent premature detachment of the bag liner during use.

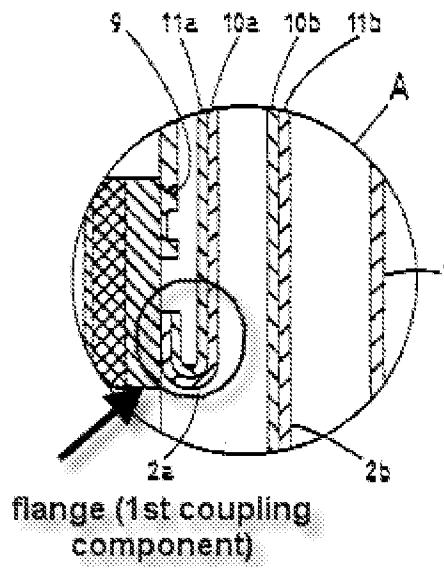


Figure 2A

16. Regarding claims 4 and 5, a peel strength of the adhesive sealing of the first coupling means taught by Smith is necessarily greater than a peel strength of the second coupling means, as Smith teaches double sided tape for the second means 12 (Col. 4, lines 39-41), which is a releasable means of coupling, whereas Smith teaches welding for the first coupling means (Col. 4, lines 33-35), which is a permanent mechanical attachment and thus has a greater peel strength.

17. Regarding claim 6, Smith discloses that the flange of the inner bag liner 2 is provided with a siliconized surface (Col 3, lines 21-26) on the side facing the flange of the receiving member in the third coupling area.

18. Regarding claim 8, Smith discloses the inner bag liner 2 is provided with a membrane allowing intestinal gas to escape (Col 3, lines 5-6) but is impermeable to liquids (Col 3, line 16).

19. Regarding claim 9, Smith discloses an adhesive wafer in the form of an adhesive flange 3 (Fig 2) having a first hole for receiving a stoma, ureter, or catheter, said adhesive wafer 3 having a first surface to be attached to the wearer's abdomen (Smith refers to flatus gases, which are intestinal gases) and a receiving member 1 attached to the adhesive wafer 3, said member having a second hole for receiving wastes exiting the stoma, ureter or catheter; and a disposable inner bag liner 2 forming a second bag inside the receiving member 1 and being releasably attachable to the adhesive wafer 3 by first coupling means, said disposable inner bag 2 liner having a third hole for receiving wastes exiting the stoma, ureter or catheter, the first coupling means being in the form of an adhesive flange projecting from a rim of the third hole (indicated generally at item 2a in Fig 2A) and having a surface for releasable sealing against a first surface of the adhesive wafer 3 (Smith teaches that the bag liner 2 is welded to the wafer 3 and has a first surface for sealing against a first surface of the adhesive wafer), wherein the inner bag liner 2 is provided with folding lines for compacting the bag lengthwise. Figure 2 of Smith shows the bag in its compacted state. (Cols 4 and 5, all lines)

Smith teaches that inner bag liner 2 is welded to base plate 3 (first coupling means) and thus does not teach that the bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling means. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer bag 1 to the base plate 3. Therefore, it would be obvious to one of ordinary skill in the art to modify the article of Smith such that bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling

means, i.e. the adhesive flange projecting from the rim of said third hole, with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2. The first coupling means of the article fairly suggested by Smith has a surface for releasable sealing against a first surface of the adhesive wafer and is in the form of an adhesive flange.

Smith does not specifically disclose that the fold lines form spiral lines. However, the inner bag liner of Smith would be capable of having spiral lines in its compacted position. Applicant has not provided what is the criticality of having the fold lines be spiral in shape.

20. Regarding claim 10, Smith discloses the inner bag liner is compacted lengthwise to form a disc-like structure having an outer diameter. (Figs. 2,4) Examiner's position regarding whether the structure is disc-like is based upon the fact that the structure is generally circular and flat. However, Smith does not teach that the outer diameter of the disc-like structure is less than the inner diameter of the first coupling means. However, this is achieved by merely changing the placement of the folds. Since the bag liner 2 is limited by its own size and the size of the outer receiving member/bag 1, there are only a finite number of fold placements that can be achieved such that the liner meets the remaining claim limitations and still fits within the receiving member/bag. Further, Smith teaches that bag liner 2 is disposable. The task of disposal of bag liner 2 would be made easier by a compacted bag liner 2 whose outer diameter when compacted is less than the inner diameter of the first coupling means and the third hole. This would mean that the bag liner 2 is unobstructed, and this configuration would facilitate easy grasping and pulling of the bag liner 2 out of the outer bag 1 for disposal. It would thus be obvious to one of ordinary skill in the art to modify the article of Smith such that the outer diameter of the disc-like

structure of bag liner 2 when compacted has an outer diameter that is less than the inner diameter of said first coupling means so as to provide an unobstructed path for removal and disposal of a used bag liner 2.

21. Regarding claim 11, Smith discloses the folding lines of the inner bag liner form bellows when compacting the bag lengthwise (Fig 2). Smith does not specifically disclose that the fold lines form spiral lines. However, the inner bag liner of Smith would be capable of having spiral lines in its compacted position. Applicant has not provided what is the criticality of having the fold lines be spiral in shape.

22. Regarding claim 12, Smith discloses the folding lines of the inner bag liner form telescopic bellows when compacting the bag lengthwise (Fig 2). Smith does not specifically disclose that the fold lines form spiral lines. However, the inner bag liner of Smith would be capable of having spiral lines in its compacted position. Applicant has not provided what is the criticality of having the fold lines be spiral in shape.

23. Regarding claim 15, Smith discloses a disposable inner bag liner 2 for receiving effluents or waste products of the body and for use together with an ostomy appliance comprising an adhesive wafer in the form of an adhesive flange 3 to be attached to the wearer's abdomen (Smith refers to flatus gases, which are intestinal gases) and a receiving member 1 having a hole for receiving wastes exiting the stoma, ureter or catheter, said disposable inner bag liner 2 having a hole for receiving wastes exiting the stoma, ureter or catheter and being capable of forming a bag inside the receiving member 1 and being releasably attachable to the adhesive wafer 3 in a first coupling area by first coupling means, the first coupling means being in the form of an adhesive flange projecting from a rim of the hole (Fig 2A) and having a surface for releasable sealing

against a surface of the adhesive wafer, wherein the inner bag liner 2 is provided with folding lines for compacting the bag lengthwise (as shown in Fig 2 of Smith) (Cols 4 and 5, all lines).

Smith teaches that inner bag liner 2 is welded to base plate 3 (first coupling means) and thus does not teach that the bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling means. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer bag 1 to the base plate 3. Therefore, it would be obvious to one of ordinary skill in the art to modify the article of Smith such that bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling means, i.e. the adhesive flange projecting from the rim of said third hole, with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2. The first coupling means of the article fairly suggested by Smith has a surface for releasable sealing against a first surface of the adhesive wafer and is in the form of an adhesive flange.

Smith does not specifically disclose that the fold lines form spiral lines. However, the inner bag liner of Smith would be capable of having spiral lines in its compacted position. Applicant has not provided what is the criticality of having the fold lines be spiral in shape.

24. Regarding claim 16, the inner bag liner 2 taught by Smith is provided with a membrane comprised of water-impermeable material such as polyvinyl alcohol, which inherently and necessarily allows intestinal gas to escape but is impermeable to liquids, as polyvinyl alcohol film is only gas-permeable.

25. Regarding claims 17, 18, 19 and 28, Smith does not explicitly disclose how many revolutions a bottom part of the bag is rotated in relation to a rim part of the inner bag liner. However, Smith's

bag is capable of performing this rotation. Furthermore, these claims do not further limit the device structurally and only provide functional specifications.

26. Regarding claim 20, Smith discloses an ostomy appliance comprising a base plate in the form of a flange 3, said base plate having a first hole for receiving a stoma, ureter, or catheter and an adhesive wafer 4 having a first surface to be attached to the wearer's abdomen, back, or chest (Fig 5); a receiving member 1 releasably attached to the base plate 3 via double sided tape 12, said member 1 having a second hole for receiving wastes exiting the stoma, ureter or catheter (Fig 2); and a disposable inner bag liner 2 forming a second bag inside the receiving member 1 and being releasably attachable to the base plate 3 in a first coupling area by first coupling means, said disposable inner bag liner 2 having a third hole for receiving wastes exiting the stoma, ureter or catheter and the receiving member 1 being releasably attachable to the base plate 3 in a second coupling area by second coupling means, the first coupling means being in the form of an adhesive flange projecting from a rim of the third hole (indicated generally at item 2a in Fig 2A) and having a surface for releasable sealing against a second surface of the base plate 3 facing away from the user, wherein the inner bag liner 2 is provided with folding lines for compacting the bag lengthwise (Fig 2) (See also Cols 4 and 5, all lines). Smith teaches the steps of locating the stoma, applying the base plate and locating the inner bag liner (Figs. 5 and 6). The step of attaching the receiver member 1 to the base plate 3 is accomplished by the welding of the bag liner 2 to base plate 3, as the first coupling area as disclosed includes said base plate 3 (Abstract). (Cols. 4 and 5, all lines)

Smith teaches that inner bag liner 2 is welded to base plate 3 and thus does not teach that the bag liner 2 is reattachably attachable to the base plate 3 in a first coupling area by a first

coupling means. However, Smith teaches that welding and double sided adhesive tape are equivalent means for attaching outer bag 1 to the base plate 3 and teaches that bag liner 2, not outer receiving member/bag 1, is disposed of after a single use, therefore it would be obvious to one of ordinary skill in the art to modify the article of Smith such that bag liner 2 is releasably attachable to the base plate 3 in a first coupling area by a first coupling means, i.e. the adhesive flange projecting from the rim of said third hole with a reasonable expectation of success to provide quicker releasable attachment of the disposable single-use bag liner 2.

Smith teaches a release liner 5 protecting adhesive layer 4. Smith does not explicitly teach the step of removing a release liner covering said first coupling means. However, Smith fairly suggests an adhesive first coupling means that comprises double sided tape for reasons stated *supra* in this rejection, and it is well known in the art to provide a release liner to protect an adhesive layer from contamination that is removed just prior to use. Thus, it would be obvious to one of ordinary skill in the art to modify the method fairly suggested by Smith wherein the first coupling means is double sided adhesive tape, to include the step of removing a release liner covering said adhesive first coupling means with a reasonable expectation of success as the step of removing the liner implies the existence of such liner which prevents contamination of the adhesive first coupling means suggested by Smith.

Smith does not specifically disclose that the fold lines form spiral lines. However, the inner bag liner of Smith would be capable of having spiral lines in its compacted position. Applicant has not provided what is the criticality of having the fold lines be spiral in shape.

27. Regarding claims 21 and 22, Smith discloses a bag 2 (Fig 2) comprising a bottom part (the weld point of the two sheets 2b) and a sidewall 2b (Fig 2) extending from the bottom part to

a rim 2a (Fig 2A) of the bag, the bag being compacted lengthwise while twisting the bottom part in relation to the rim such that folding lines on at least a part of the sidewall. Smith's bag is capable of performing this twisting. Furthermore, these claims do not further limit the device structurally and only provide functional specifications.

Smith does not specifically disclose that the fold lines form spiral lines. However, the inner bag liner of Smith would be capable of having spiral lines in its compacted position. Applicant has not provided what is the criticality of having the fold lines be spiral in shape.

28. Regarding claim 23, Smith discloses that the bottom part (the weld point of the two sheets 2b) is substantially planar as shown in Figure 2.

29. Regarding claims 24, 25 and 26, Smith discloses the bag 2 (Fig 2) is an inner bag liner and may be used for an ostomy (Col 3, lines 62-65).

30. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (U.S. Patent No. 5,591,144) in view of Wolrich (U.S. Patent No. 5,423,782).

31. Regarding claim 5, an outer diameter of the first coupling means of Smith (the adhesive flange extending from the rim of said third hole) is smaller than an inner diameter of the second coupling means 12.

Smith does not teach that the second coupling means is in the form of one or more coupling rings. Wolrich teaches an ostomy bag having a receiving member in the form of an outer bag and an inner bag liner. Wolrich teaches a second coupling means as disclosed in the form of coupling means 18 comprised of a ring-shaped flange coupling 18 that mates with ring 34, i.e. one or more coupling rings. As can be seen in Fig. 1, the outer diameter of first coupling means 46 is less than the inner diameter of first coupling means 46. ('782, Col. 5, lines 10-20)

Since the structure of the articles of Smith and Wolrich are substantially identical and seek to solve a similar problem in the art (i.e. provide an ostomy waste collector having a bag and an inner liner attachable to a stoma to collect waste therefrom), it would be obvious to one of ordinary skill in the art to modify the article of Smith such that the instant second coupling means (double sided tape) is replaced by the second coupling means of Wolrich to maintain the ability of the article of Smith to releasably attach to a stoma for waste collection and easier disposal.

32. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (U.S. Patent No. 5,591,144) in view of Cisko, Jr. et al. (US 5,865,819; hereinafter Cisko).

33. Regarding claim 13, Smith discloses the claimed invention including an inner bag liner 2 (Fig 2) but does not specifically disclose a cover. However, Cisko discloses the use of a cover 24 (Fig 3) to ensure that the outer pouch 11 (Fig 3) stays in its desired location until the user desires to change the configuration of the ostomy appliance. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Smith's reference, to include a cover, as suggested and taught by Cisko, for the purpose of ensuring that the inner bag liner stays in its desired location until the user desires to change the configuration of the ostomy appliance.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENEDICT L.C. HANRAHAN whose telephone number is (571)270-7854. The examiner can normally be reached on Monday-Friday, 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. L. H./  
Examiner, Art Unit 3761

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761